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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/842,161	04/26/2001	Hidetaka Iwai	206580US0	6889

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EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/842,161

Applicant(s)

IWAI ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 18, 2002 has been entered. Claims 1-25 are pending.

Claim Objections

Claims 6, 7, and 18 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In this case, claims 6, 7, and 8 fail to further limit the subject matter since the claims recite mere purpose of use of the composition of claim 1. See MPEP 2111.02.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-3, 6-8, and 10-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu (English Translation of JP 63-126542 provided herewith).

Yu teaches transparent microemulsions containing hydrophilic ionic surfactants and oil components used for pharmaceuticals and cosmetics. See p. 2, lines 1 –17; p. 7,

lines, 9-10. The reference teaches that the ratio of the nonionic surfactant to the oil ingredients in the invention may range from 1:05 to 1:10, and the emulsified particle size is 0.01-0.1 microns. See instant claims 1 and 3. See p. 4, lines 11-12. The application of the invention, such as liquid detergent, shampoo, hair tonic, etc, are disclosed in p. 7, lines 19-24. See instant claims 19.

Although Yu lacks a specific example formulation having the ratio of oil to hydrophilic surfactants, which is greater than or equal to 10:1, the ratio of 10:1 is taught to be useful. Thus, one having ordinary skill in the art at the time of the invention was made would have had expected to successfully formulate a transparent microemulsion having such high oil to hydrophilic surfactant ratio.

The reference teaches anionic surfactants, cationic, amphiphilic surfactants, or mixture of thereof in p. 4, line 12 – p. 5, line 5. Monosodium alkyl glutamate is taught. See instant claims 11-13. While the Yu reference does not teach dynamic surface tension of these surfactants, examiner notes that the prior art surfactants are within the obvious range of the claimed limitation and no criticality of the specific recited surface tension is shown. See *infra*, Response to Arguments.

Examiner also notes that instant claims 1, 6, 7, and 15 are product-by-process claims. It is well settled in patent law that “if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” See MPEP § 2113, quoting In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, given the presumption of the obviousness of the product itself, the process of making

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thereof will not be given patentable weight. Nevertheless, the limitations are obvious view of the Yu reference teaching, in p. 7, lines 4- 8, to use a high pressure homogenizer or ultrasound emulsifying machine to produce strong shear stress of 400 atm or higher, or preferably of 600 atm or higher at a temperature below 50 °C. See instant claim 20. Examiner takes the position that employing the prior art equipments would obviously produce the shearing rate of the instant claims, unless proven otherwise.

2. Claims 4, 5, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-4, 6-8, and 10-21 above, and further in view of Drapier et al. US 6121228 ("Drapier").

Yu further teaches that while liquid oils are preferred, oils in solid state may be used if they become liquid when mixed, suggesting mixing liquid and solid fatty components. See p. 5, line 6 – p. 6, last line. See also Tables for high alcohols, such as isostearyl alcohol, showing satisfactory transparent microemulsions. The Yu reference fails to teach an example of composition having both solid and liquid oil with specific viscosity.

Drapier teaches water-in-oil microemulsion liquid detergent having viscosity ranging from 6-300 milliPascal. See col. 4, lines 47 – 67; col.14, lines 17 - 26.

Given the teaching in Yu that the both liquid and solid oils may be used for variety of microemulsion applications such as liquid detergents, and the teaching that thickening agents may be added in the compositions, it would have been obvious to one

having ordinary skill in the art to have expected successfully producing a product having desired viscosity by routine experimentations. The routineer who contemplates to formulate the liquid detergent according to Yu would have been motivated to adjust the viscosity as taught by Drapier.

3. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-4, 6-8, and 10-21 above, and further in view of Ansel (Pharmaceutical Dosage Forms and Drug Delivery Systems, 1990 5th ed.).

While Yu teaches that the HLB of the ionic surfactants should be hydrophilic since it is necessary to obtain oil-in-water type microemulsions, the reference fails to teach HLB of the surfactants.

Ansel teaches that surfactants having HLB of 8-18, and particularly HLB of 15-18 produce transparent microemulsion compositions. See Ansel, p. 244 col. 2, lines 9-13.

Given the general teaching of formulating o/w microemulsion compositions in Yu, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to look to the prior arts such as Ansel for specific types and characteristics of the emulsifiers conventionally used in microemulsions.

4. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-4, 6-8, and 10-21 above, and further in view of Gers-Barlag et al. (US 5876702) ("Gers-Barlag").

The Yu reference fails to teach the surface tension of the oil components.

Gers-Barlag teaches that o/w microemulsions are obtained from oil components having surface tension of less than 30 mN/m. See col. 17, lines 15 – 30. The reference teaches that oils having a polarity between 10-20 mN/m are preferred. See also col. 17, lines 31 – 46 for specific types of oils.

Given the general teaching of formulating o/w microemulsion compositions in Yu, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to look to the prior arts such as Gers-Barlag for specific types and characteristics of oils conventionally used in microemulsions.

5. Claims 23 and 25 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Yu as applied to claims 1-4, 6-8, and 10-21 above, and further in view of Diec et al. (US 6468551 B1) ("Diec").

Yu, discussed above, fails to teach using silicone oil in the microemulsion. Diec teaches cosmetic o/w microemulsions comprising hydrophilic o/w emulsifiers. See Example 22, comprising oil and the emulsifier in the weight ratio of greater than 10:1. See also col. 45, lines 31-39. The reference teaches that silicone oils are "advantageously" used in the invention, particularly mentioning polydimethylsiloxanes. See col. 25, lines 43 – 53. See instant claim 23 and 25.

Given the general teaching of formulating o/w microemulsion compositions in Yu, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have been motivated to look to the prior arts such as Diec for specific types oils conventionally used in microemulsions for cosmetic purposes. The skilled

artisan would have expected to successfully produce a cosmetically advantageous composition.

6. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu as applied to claims 1-4, 6-8, and 10-21 above, and further in view of Brunetta et al. (US 5562911) ("Brunetta").

Yu, discussed above, fails to teach fluoro-based oil.

Brunetta teaches that due to the formation of protective film on skin, the use of perfluoropolyether in cosmetic formulation is well known in the art. See col. 1, lines 15 – 56.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substitute the oil in the Yu formulation with perfluoropolyether as motivated by Brunetta, because of the expectation of successfully producing a o/w microemulsion which forms protective film on the skin.

Response to Arguments

Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

Applicants' declaration filed on December 24, 2002, has been considered but is not persuasive for the reasons stated above. To rebut the presumption of obviousness, applicants must show unexpected results of the invention by clear and convincing evidence that commensurate with the scope of the claims. See MPEP § 716.02. In this case, Applicants' declaration does not commensurate with the scope of the claim. Applicants indicate that the prior art surfactants used in the example formulation have

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surface tension slightly above 57 mN/m, and suggest that low transparency is obtained by using these surfactants in a particular formulation shown in declaration p. 2.

However, the scope of the present invention is not limited to that particular formulation.

Applicants' earlier disclosure in the specification and the Yu reference indicate that surfactants such as cetyltrimethylammonium bromide, whose surface tension is 65.7 mN/m, according to declaration, still effectively produce a transparent microemulsion.

See specification p. 20, line 1- p. 21, line 3. Examiner further notes that those surfactants having surface tension below 57 mN/m, such as sodium alkyl glutamate, are also disclosed in the Yu reference. Thus, absent the criticality of the recited surface tension within the scope of the claim, that limitation is viewed obvious over the prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

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Gina C. Yu
Patent Examiner
February 10, 2003


SREENI PADMANABHAN
PRIMARY EXAMINER

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